# WHO Public Health Laboratories
## knowledge sharing webinar

2nd February 2022

# SARS-CoV-2 variants – updates on the virus biology and diagnostics performance

In this webinar, we had an update on the global circulation of SARS-CoV-2 variants, virus biology and diagnostics performance; and heard about the processes used by WHO to list products (Emergency Use Listing, EUL) and monitor diagnostic performance. We also heard experiences from colleagues in Australia on the protocols used for verification of test performance.

**Dr Amy Mikhail** provided an update on the Omicron variant, taking us through phylogeny, diversity, and diagnostic challenges, highlighting the increase in BA.2 relative to the other Omicron lineages, which has become dominant in 9 countries. This lineage does not have the 69-70 deletion posing diagnostic challenges to its detection, and may have similar immune escape capacity to BA.1, pending confirmation. The rapid rise of Omicron cases at a global level has highlighted the importance of strengthening and improving genomic surveillance, in preparation for other variants that may emerge in the future.

**Dr Ute Ströher** shared an overview of the WHO Emergency Use Listing (EUL) requirements and procedures, and instructions for submission, emphasizing necessary manufacturer considerations around current and future VOC mutations that may affect test performance. All currently listed products are able to detect Omicron, however in-silico analysis has shown possible mismatches in one of the two or three targets of some dual/triple target assays, potentially reducing sensitivity, highlighting the importance of further studies.

**Ms Anita Sands** presented on post-market surveillance, highlighting the need for this to be a continuous process ensuring the safety, quality and performance of products given the dynamic nature of arising VOCs; and described the three-pronged risk assessment process to ensure EUL products continue to meet WHO requirements, giving some practical examples and updates on the current review status; and ended with some advice for product end users to contribute towards PMS by documenting and reporting any product issues with the user feedback form.

**Prof Deborah Williamson** described the laboratory perspective on the performance assessment of rapid antigen tests, taking us through the purpose of conducting such an evaluation; differences between analytical and clinical performance; a review of methodological differences, highlighting the challenges of interlaboratory comparisons; and presenting a minimum reporting framework based on a set number of requirements for standardization in antigen performance studies, and finalising on a note that in addition to analytical studies, clinical studies are crucial to understand overall test performance.


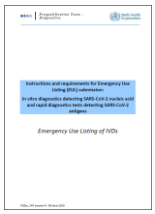


*Image credit: Nathalie Worp, Erasmus MC (available here: https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/)*

Arabic, English, French, Russian, Spanish and Portuguese

1889 Participants registered

155 Countries

64% female, 35% male, 1% prefer not to say

35 Questions asked

## Speakers

**Dr Amy Mikhail-** WHO Headquarters, Geneva

**Dr Ute Ströher-** WHO Headquarters, Geneva

**Ms Anita Sands-** WHO Headquarters, Geneva

**Prof Deborah Williamson-** Victorian Infectious Diseases Reference Laboratory (VIDRL), Australia)


***To contact us:***

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***Useful links*** *(click on blue text)*

Webinar recordings * : English - Français – Русский – Português – Español - عربى

Presentations: Dr Mikhail – Dr Ströher – Ms Sands – Dr Williamson

Questions answered by the presenters: EN

**WHO guidance documents**

Enhancing response to Omicron SARS-CoV-2 variant – Emergency Use Listing procedure -Guidance for post-market surveillance and market

* The interpretation of proceedings serves to facilitate communication and does not constitute an authentic verbatim records of the proceedings. Only the original speech is authentic.


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